ISSUE No. 45

SILVER JUBILEE YEAR 2016

TAMILNADU PHARMACEUTICALS SCIENCES WELFARE TRUST

25 Years

e-NewsLetter

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

Jan. - Feb. - Mar. 2020

Delvin Formulations

Destiny for Innovation

Moving Globally

- R & D and Manufacturing of API
- R & D and Manufacturing of Formulations
- International Marketing
- Domestic Marketing
- Medical Devices
- Surgicals

Our Group of Companies

NURAY CHEMICALS PVT. LTD.	Sai Mirra Innopharm Pvt. Ltd.	Delvin Formulations	Numen (Singapore) Healthcare Pvt. Ltd.	Delvin Klarvoyant Biogenics Pvt. Ltd.	Delvin Surgicals
R & D and Manufacturing of API	R & D and Manufacturing of Formulations	Domestic Marketing	International Marketing	Medical Devices	Surgicals

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Tamilnadu Pharmaceutical Sciences Welfare Trust

Pharma Web

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TAMILNADU PHARMACEUTICAL SCIENCES WELFARE TRUST
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e-mail : pictrust@hotmail.com Website : www.pictrust.com

EDITORIAL

Dear Readers,

We are happy to publish the 45th issue of Pharma Web Newsletter for Jan – Mar 2020.

We regret to inform the delay in publishing this issue, due to COVID 2019 and we are decided to publish e-newsletter of this issue. We are sending this issue through email and What's app, and the forthcoming issues will send by hard copy.

This 45th issue contains the following lectures given by various resource persons, the seminar which was conducted by Pharmexcil, in Chennai, on 15th February 2020.

- Regulatory Strategy for Emerging Markets - **Mr. Sadiq Bashah**, Vice President – Regulatory Affairs, Strides Pharma Science Ltd., Bangalore

- Indian Pharma Exports Unlocking the Potential for SMEs - **Ms. Lakshmi Prasanna**. Ch, Sr Regulatory Affairs Officer, Pharmexcil, Hyderabad

We have published the various Gazette Notifications pertaining to the amendment of Drugs & Cosmetics Act & Rules and also important circulars issued by DCGI.

Important news items connected to our Pharmacy profession appeared in various national news papers are published in this issue.

We are very much thankful to M/s. Delvin Formulations, M/s. Medopharm, M/s. Tablets (India) Ltd., M/s. Acid India Ltd., for the continuous support by giving advertisement, in order to sustain the cost of publishing of this newsletter.

Our special thanks to M/s. Fourrts (India) Laboratories Pvt. Ltd., for supporting Pharma Web advertisement and also awarding meritorious award for B. Pharm Students of The Tamilnadu Dr. MGR Medical University, Guindy, Chennai.

Hope this Newsletter will benefit our Pharma professionals. Any suggestions to improve our news letter are welcome.

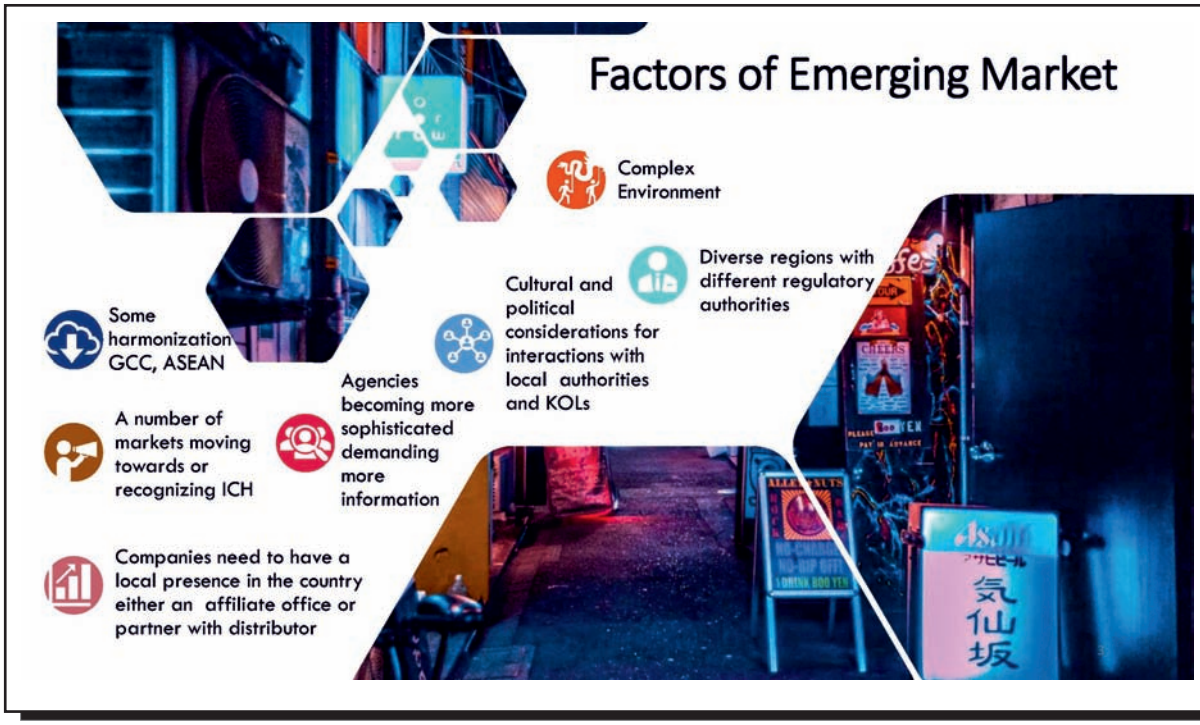
With Best Regards,
R. NARAYANASWAMY
Chief Editor

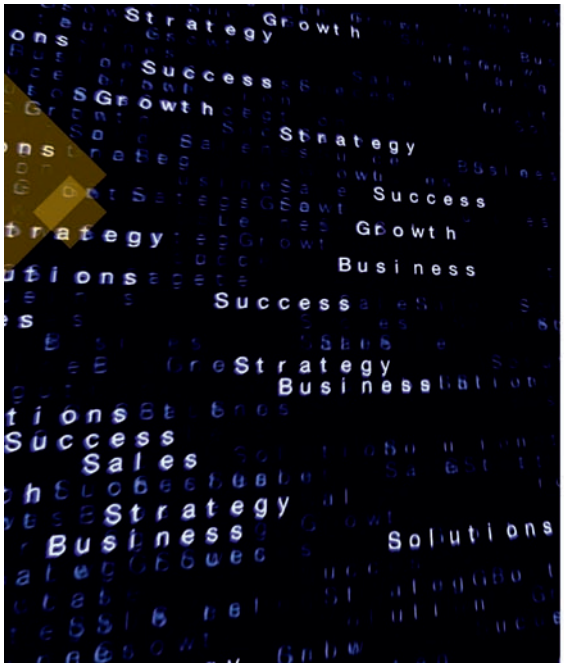
ARTICLES

REGULATORY STRATEGY FOR EMERGING MARKETS

by

Mr. Sadiq Bashah,
Vice President – Regulatory Affairs, Strides Pharma Science Ltd., Bangalore
(Lecture Delivered during the Seminar on ""Recent Advancements in Regulatory landscape of India & Emerging Markets" held on 15th February 2020, conducted by Pharmexcil.)





CONSIDERATIONS TO ENTER EMERGING MARKET

- Enter market quickly avoid the lag behind EU and US approvals
- Include EM strategy in the Integrated Product Development
- Decisions taken during early product development will impact success in EM

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DID YOU KNOW?

World population

- **4.5%** - USA
- **6.8%** - EU
- **60%** - Asia

In the next **10 minutes**

- **77** children will be born in the US
- **100** children will be born in EU
- **1000** children will be born in India and China

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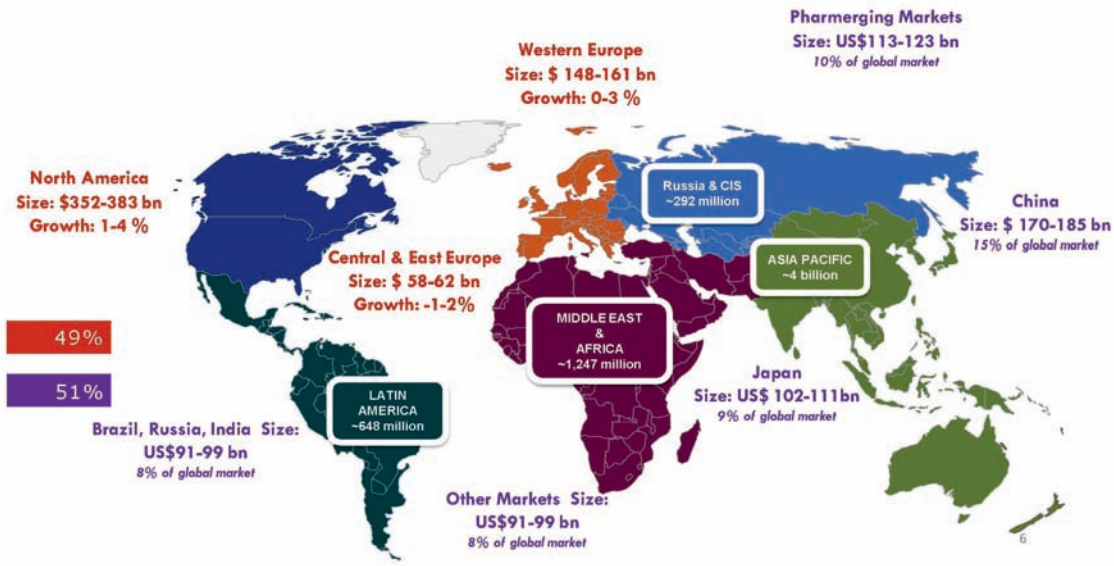
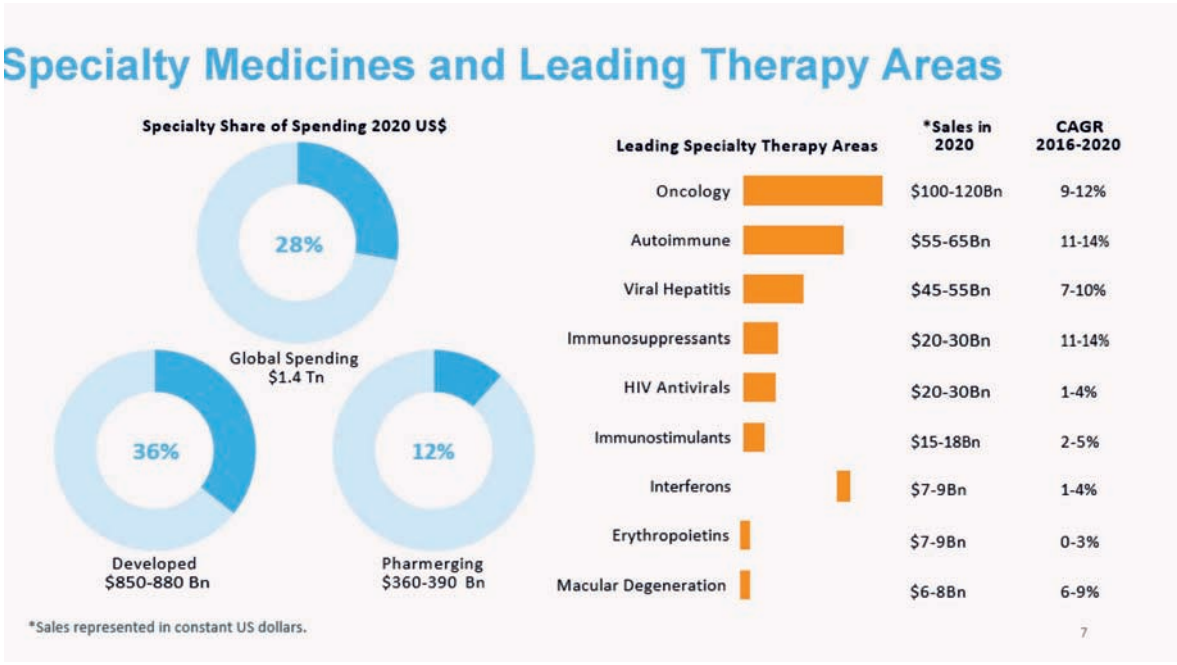
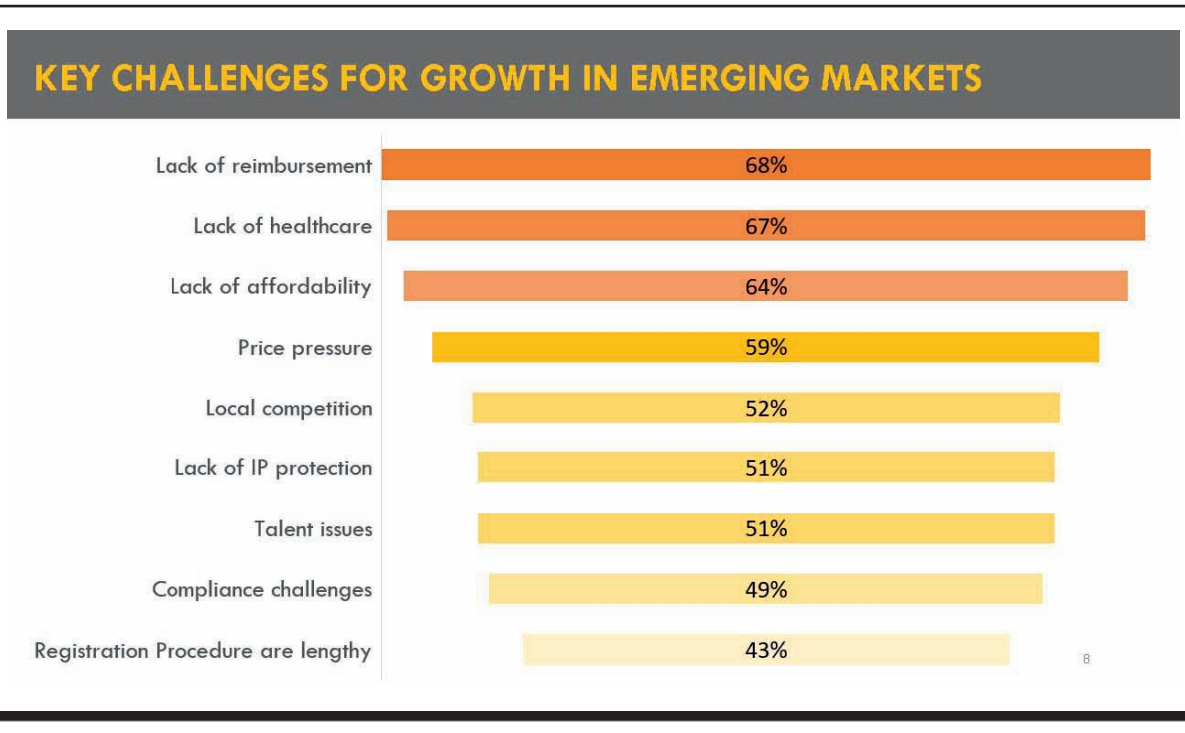
EMERGING MARKETS & GLOBAL SHARE




Specialty Medicines and Leading Therapy Areas
Specialty Share of Spending 2020 US$
28%
Global Spending
$1.4 Tn
36%
12%
Developed
$850-880 Bn
Pharmerging
$360-390 Bn
*Sales represented in constant US dollars.
Leading Specialty Therapy Areas
*Sales in 2020
CAGR 2016-2020
Oncology $100-120Bn 9-12%
Autoimmune $55-65Bn 11-14%
Viral Hepatitis $45-55Bn 7-10%
Immunosuppressants $20-30Bn 11-14%
HIV Antivirals $20-30Bn 1-4%
Immunostimulants $15-18Bn 2-5%
Interferons $7-9Bn 1-4%
Erythropoietins $7-9Bn 0-3%
Macular Degeneration $6-8Bn 6-9%
7


KEY CHALLENGES FOR GROWTH IN EMERGING MARKETS
Lack of reimbursement 68%
Lack of healthcare 67%
Lack of affordability 64%
Price pressure 59%
Local competition 52%
Lack of IP protection 51%
Talent issues 51%
Compliance challenges 49%
Registration Procedure are lengthy 43%
8

EMERGING MARKET REGIONS

Latin America | Africa and Middle East | Russia and CIS | Asia Pacific

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LATIN AMERICA MARKET OVERVIEW

- LA market historically constituted 5-7% of the global market share ($62.9 billion in sales in 2011) and registered a growth of 8.9% in 2012.
- Clinical research mostly established and centered in Mexico, Argentina and Brazil, with Chile, Colombia and Peru rapidly evolving.
- Market expected to grow at 10-13% by 2016 in Brazil, Argentina, Colombia, Chile, Peru and Venezuela.

- LA continued growth as a clinical trial market
- 5.1% of the world's clinical research spending in 2019
- ~4000 clinical trials currently run.

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LATIN AMERICA – REGULATORY REQUIREMENTS

	Brazil (ANVISA)	Argentina (ANMAT)	Chile (ISP) and Colombia (INVIMA)	Mexico (COFEPRIS)	Peru (DIGEMID) and Venezuela (INHRR)
Dossier Format	**CTD**	**Country specific**	**CTD – electronic and paper**	**Country specific**	**Country specific**
Registration fees	5100 Rias	2300 Rias	USD 2231 – Chile USD 150 - Colombia	60,100 Mexican pesos 160,000 pesos (Fast Track)	USD 125 - 175
Labelling	Portuguese	Spanish	Spanish	Spanish	Spanish
Documents	COPP – Country Specific Stability at 30/75. Repetition of release testing during commercialization	COPP – Country Specific Stability at 30/75. Repetition of release testing during commercialization	COPP – Country Specific Stability at 30/75. Repetition of release testing during Commercialization. Not required at Colombia	COPP – Country Specific Stability at 25/60 Repetition of release testing during commercialization	COPP – Country Specific Stability at 25/60. Performed by certified laboratory as part of registration at Venezuela

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RUSSIA AND CIS MARKET OVERVIEW

Russia and CIS markets have a major share of the global market share

Government aiding in Healthcare

Market has 4% of global share

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RUSSIA AND CIS MARKET

	Armenia, Azerbaijan, Georgia Kyrgyzstan, Moldova Tajikistan, Turkmenistan Mongolia	Belarus, Kazakhstan, Uzbekistan	Russia	Ukraine
Mutual recognition (MR) & WHO Collaborative procedure*	**Armenia, Azerbaijan Georgia (US & EU – MR acceptable) Kyrgyzstan**	**Belarus Kazakhstan Uzbekistan**	-	**Ukraine (US & EU – MR acceptable)**
Plant inspection	Not required	Required	Required	Required / Disk audit based on PIC's approval
Labelling	English and French	Russian & Local language	Russian with QP details	Ukrainian
Documents Mfg. lic, GMP, COPP, FSC MFR, PDR, DMF, RM, PM, FP Spec STP &, COAs, PV, AMV. BE required Stability data [3 batch] [Zone II or Zone IV]	Samples: Total 300 + W/S	Additionally, Product lic and FSC (Apostilled) FP samples – quantity required Ref. / working std, HPLC column for 3-time analysis,	Additionally, Product lic and FSC (Apostilled). FP samples - quantity required Ref. / working std, HPLC column for 3-time analysis	Additionally, Product lic and FSC (Apostilled). FP samples - quantity required Ref. / working std, HPLC column for 3-time analysis.

AFRICA OVERVIEW

- 1 billion inhabitants
- 15% of world's population
- Pharmaceutical market ~ US$ 40 Billions
- 4% of the world's market
- < 1% of worldwide clinical trials (excluding Israel which is a developed CT market)
- Predicted to increase exponentially in next decade.

Arab speaking countries
Francophone Africa markets
Non-Francophone Africa markets
Stand-alone markets

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Africa Region – Regulatory Requirements

	Cameroon, Congo, DRC, Gabon, Chad	French Africa	Nigeria	Zimbabwe, Ghana, Uganda Kenya, Ethiopia, Tanzania	Zambia, Malawi, Namibia, Botswana, Mozambique, Rwanda, Sudan, Sierra Leone
Dossier Format	Country Specific	CTD	Country Specific	CTD	Country specific Botswana - CTD
Plant inspection	Not required	No inspection done, but Plant approval is to be submitted	No inspection required. But Power of Attorney required	Inspection required and Ethiopia Legalization required	Inspection Required for Malawi
Labelling	English and French	English and French	English with distribution data	English	English Mozambique: Portuguese
Documents MFR, RM, PM, FP Spec STP, CoAs, Stability Data 3 M, labels	Additionally, BE or CDP Samples 300 + W/S	Additionally, BE or CDP, PDR, DMF, PV, AMV, Samples 700 + W/S	Additionally, BE or CDP, PDR, DMF, PV, AMV, Samples: 100	Additionally, BE, PDR, DMF, PV, AMV, Samples: 15- 50	Additionally, BE, PDR, DMF, PV, AMV, Samples: 15 each

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ASIA PACIFIC MARKET

- 60% of world's population
- The ASEAN region comprises 10 countries: Malaysia, Indonesia, Thailand, Philippines Singapore, Brunei, Vietnam, Laos, Cambodia, and Myanmar. All 10 countries are seeking economic development to improve competitiveness by eliminating trade barriers
- Epidemiology and Unmet Medical Need

ASEAN Harmonization — **Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Philippines, Singapore, Thailand, Vietnam**

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ASIA Pacific Market – Regulatory Requirements

	Singapore	Malaysia	Philippines	Indonesia	Thailand
Dossier Format	**GDA and NDA Application**	**ACTD**	**ACTD**	**Country Specific**	**GDA and NDA Application**
Plant inspection	Accepts FDA/EU/PICs approval for FP site	Accepts FDA/EU/PICs approval for FP site	Accepts FDA/EU/PICs approval for FP site	Accepts FDA/EU/PICs approval for FP site	Accepts FDA/EU/PICs approval for FP site
Labelling	English	English	English	English	English
Documents	COPP and Country Specific Requiremnt	ACTD Structure	ACTD Structure	ACTD Structure	ACTD Structure

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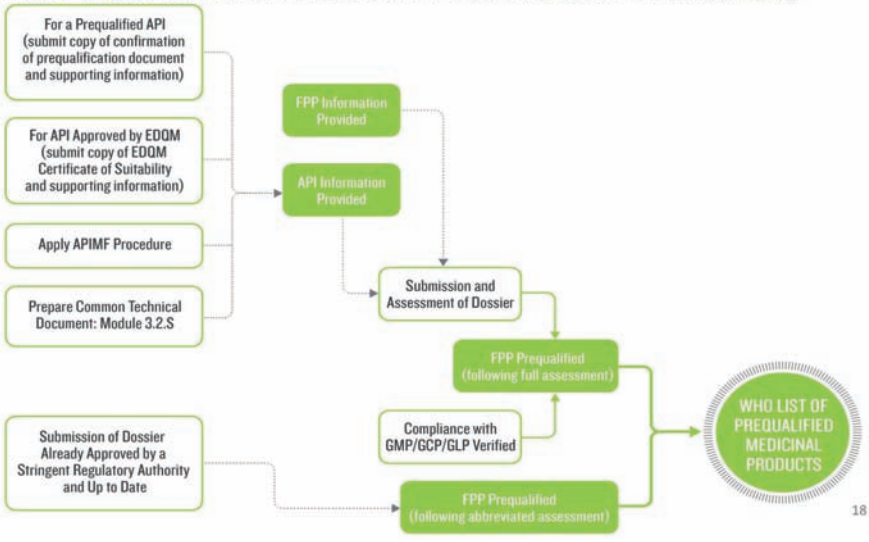
Prequalification Process in WHO

The median WHO time to prequalification has consistently been around 200 days during the past few years
The total WHO time to prequalification of an SRA-approved FPP is generally one to two months (median)



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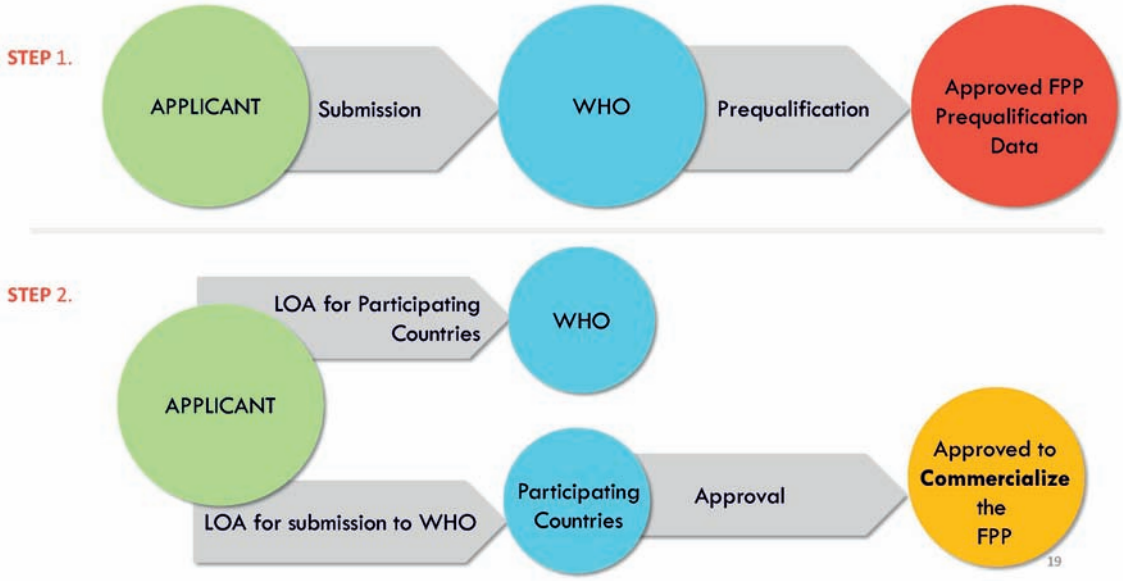
WHO: Prequalification and Participating countries



WHO: Accelerated Registration of FPPs Approved by SRAs

- Collaborative Procedure between the WHO Prequalification of Medicines Program and National Medicines Regulatory Authorities in the Assessment and Accelerated National Registration of WHO-prequalified Pharmaceutical Products.
- Participating NMRAs will use the data submitted to support their decision-making regarding registration. WHO will seek to issue an "accelerated" decision on registration within 90 days of their acceptance of the submission.

- Armenia
- Azerbaijan
- Belarus
- Bhutan
- Botswana
- Burkina Faso
- Burundi
- Caribbean Community (CARICOM)
- Cameroon
- Comores
- Côte d'Ivoire
- Democratic Republic of the Congo
- Eritrea
- Ethiopia
- Georgia
- Ghana
- Kazakhstan
- Kenya
- Kyrgyzstan
- Lao People's Democratic Republic
- Madagascar
- Malawi
- Malaysia
- Mali
- Mozambique
- Namibia
- Nigeria
- Pakistan
- Philippines
- Rwanda
- Senegal
- Sierra Leone
- South Africa
- Sri Lanka
- Sudan
- Tanzania
- Thailand
- Uganda
- Ukraine
- Uzbekistan
- Zambia
- Zanzibar
- Zimbabwe

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Emerging Market Product Development

Plan for Development of a product in Emerging market

- **Commercial Considerations**
- **Clinical**
- **Quality**
- **Submission Strategy**
- **Lifecycle Managment**

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COMMERCIAL CONSIDERATIONS

Epidemiology and Unmet Medical Need

- Prevalence of diseases in certain regions e.g. high incidents of lung head and neck liver and gastric compared to the West

Label

- Label claim can influence reimbursement if there are competitors with similar or better label
- Regulators consider label approved by Tier 1 authorities
- Essential that research is done at the start of clinical trials

IP Risks

- Threat of generics due to poor IP protection
- Compulsory Licence – there have been several cases where governments have given permission to generic companies to produce patented products or use processes without the consent of the patent owner

Reimbursement

- Local manufacturers preferred by many governments e.g. Russia, Brazil
- Pharma should work with local governments on patient access incentives donations programs flexible pricing

Tenders

- Maintaining awareness of tendering process and cycles
- Being able to service tender applications promptly and thoroughly

As patient recruitment becomes more challenging, there has been an increase in clinical trials conducted outside of EU and US e.g. Asia, Latin America, Middle East.

- A number of markets require local clinical data at time of NDA submission e.g. Russia, South Korea, Taiwan, China, Vietnam (if product on the market for less than 5 years), Nigeria, Mexico (not mandatory but could be requested)
- Important that clinical development plan includes EM considerations as early as phase II e.g. Korea will only accept data generated in Korean patients in Korea
- If considering entering any of these markets careful consideration should be made to include them in your global Phase III program or develop a regional strategy e.g. Asia development strategy including Japan, Korea, Taiwan, and China

QUALITY REQUIREMENTS

CMC

- Majority of markets will have their own format for the registration dossier, although CTD for Modules 2 – 5 is becoming acceptable in an increasing number of markets
- Some markets have harmonised procedures e.g. ASEAN CTD (ACTD)
- Variety of additional Module 1 and CMC documents not usually submitted in the EU or US some of which will require market specific authentication and legalisation

Manufacturing & Supply Chain

- The majority of markets can only register and receive supply from the manufacturing sites listed on the CPP
- Indonesia require you to have a local manufacturing plant or expect you to partner with a local manufacturer
- Some markets will only allow one manufacturing site/ supply chain site per licence, additional manufacturing sites will mean additional licenses
- Local labelling requirements need to be considered; development of market-specific or regional packs

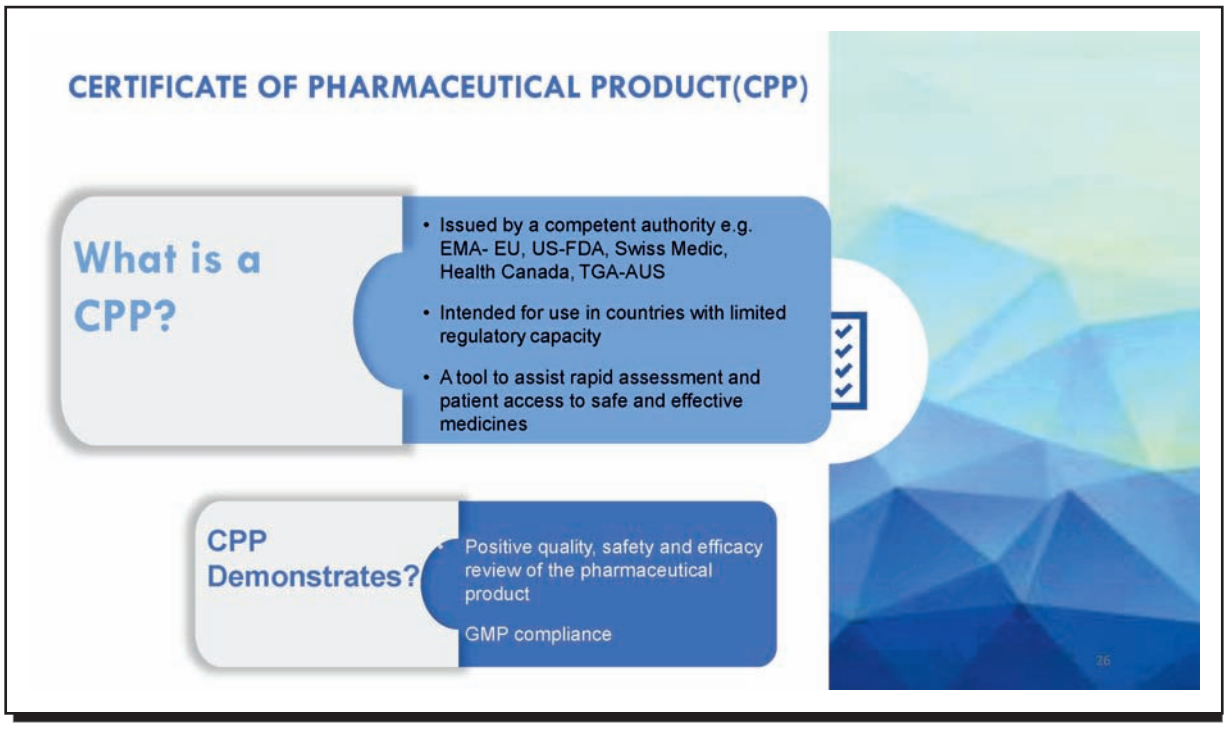
Stability

- A number of markets in Latin America, Asia and Middle East will require Zone IV stability data for NCE's 30°C/75%RH.
- Stability data at least 2 commercial scale batches may be required
- Long term stability required i.e. for a 36 months shelf life 36 months real time stability on 3 batches; extrapolation not accepted e.g. Middle East.

Formulation

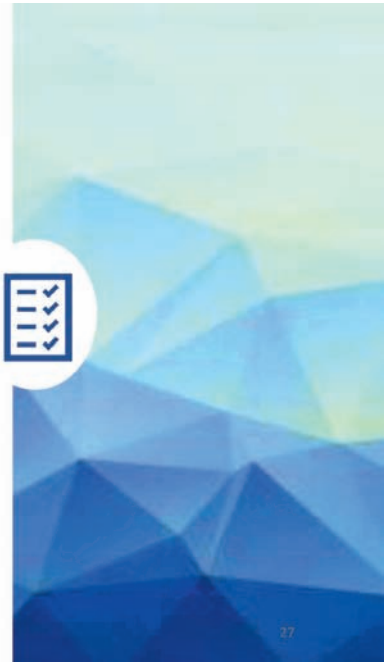
- Consideration needs to be made for Middle East and some Asia markets, porcine excipients not allowed
- Halal Certificate may be required
- Certain colours/ flavouring which contain alcohol (via fermentation) additives not permitted e.g. Egypt does not permit ethanol
- Many markets in the Middle East will not permit raw materials to be sourced from any companies with interests in Israel


CERTIFICATE OF PHARMACEUTICAL PRODUCT:
CPP
What is a CPP?
CPP Demonstrates ?

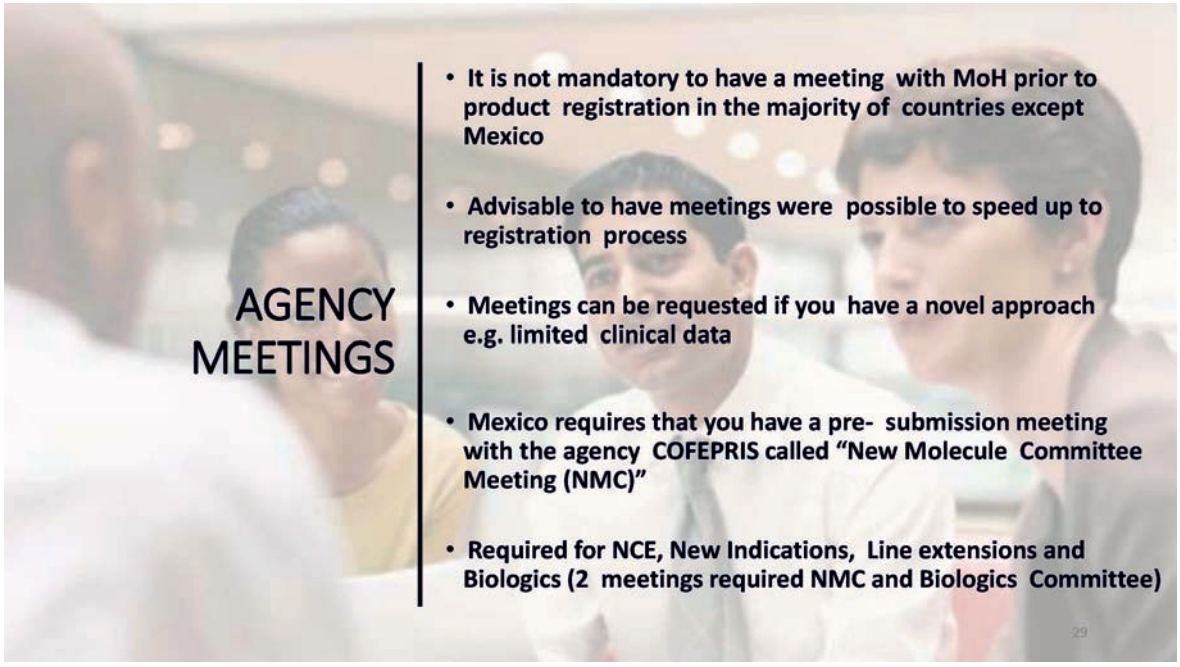

CERTIFICATE OF PHARMACEUTICAL PRODUCT(CPP)
What is a CPP?
• Issued by a competent authority e.g. EMA- EU, US-FDA, Swiss Medic, Health Canada, TGA-AUS
• Intended for use in countries with limited regulatory capacity
• A tool to assist rapid assessment and patient access to safe and effective medicines
CPP Demonstrates?
• Positive quality, safety and efficacy review of the pharmaceutical product
GMP compliance

REQUIREMENTS OF CPP

- Markets require CPP either at submission or during review or for tender submissions
- A number of markets require that the CPP is available from the country that will supply the product i.e. they cannot accept a US CPP if the supply is coming from the EU e.g. Latin America
- Some markets require more than one CPP e.g. Hong Kong
- Important that supply chain is determined early in development
- CPP needs to be Apostilled, Notarised and or Embassy Legalised
- Markets will also reference the label



Submission Strategy – Emerging Markets


AGENCY MEETINGS
• It is not mandatory to have a meeting with MoH prior to product registration in the majority of countries except Mexico
• Advisable to have meetings were possible to speed up to registration process
• Meetings can be requested if you have a novel approach e.g. limited clinical data
• Mexico requires that you have a pre- submission meeting with the agency COFEPRIS called "New Molecule Committee Meeting (NMC)"
• Required for NCE, New Indications, Line extensions and Biologics (2 meetings required NMC and Biologics Committee)
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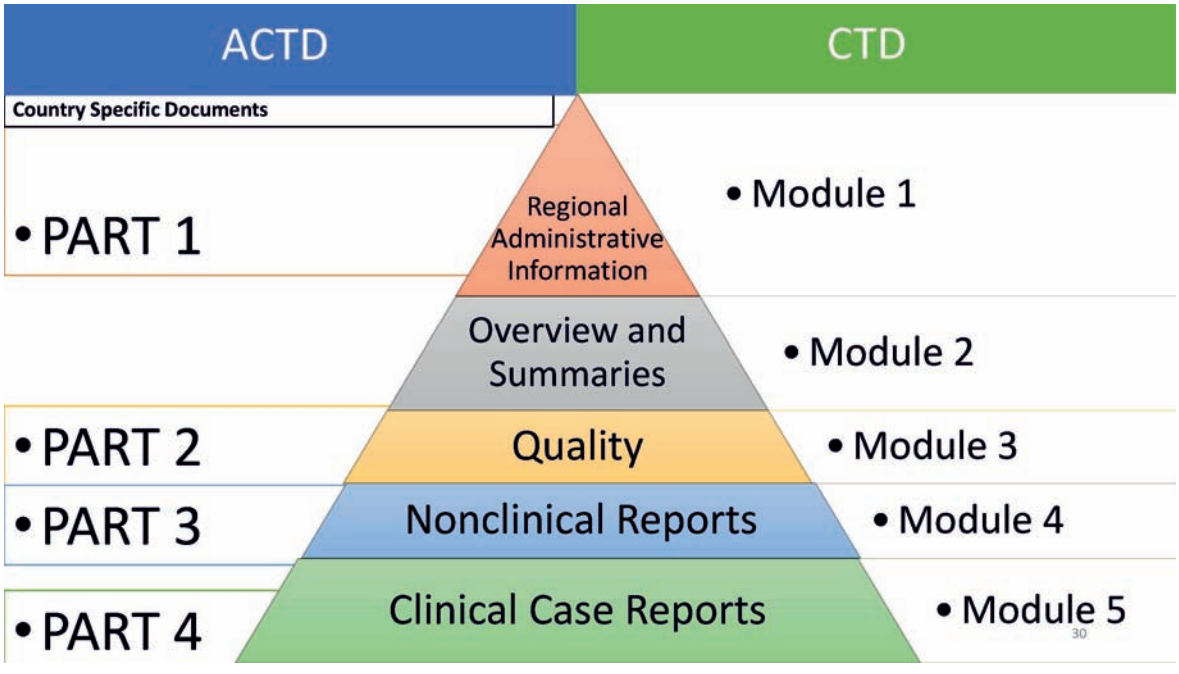
ACTD
CTD
Country Specific Documents
• PART 1
Regional Administrative Information
• Module 1
Overview and Summaries
• Module 2
• PART 2
Quality
• Module 3
• PART 3
Nonclinical Reports
• Module 4
• PART 4
Clinical Case Reports
• Module 5
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GMP APPLICATIONS & COMPANY /MANUFACTURING SITE REGISTRATION

- **The MoH will inspect the API and DP manufacturing sites over a number of days**
- **GMP Inspection required in Brazil, Argentina, China, Russia, Korea and GCC markets**
- **Need to build these into submission plan as they are required before submission of the product application e.g.**
  - Brazil – Request application 6 – 9 months before inspection
- **Site and Company Registration**
  - **Required in a number of Middle East markets**
  - **This is a separate process in some markets e.g. GCC and is required before product registration**

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POST SUBMISSION MANAGING REPONSES TO AGENCY QUESTIONS

Consolidate a plan to managing response to questions

- Approval timelines can vary from 6 months to 3+ years
- Majority of review procedures do not have clock stops
- Questions can come at any time with some markets concentrating on CMC type questions while other focus on clinical and safety
- Response times can also vary e.g. INVIMA (Chile) 5 days
- Extensive multiple rounds of questions. e.g. TFDA (Taiwan)

Ensure that team have system for tracking questions and that there is enough manpower to manage volume of questions

Ensure the manufacturer(s) are on board to respond in a timely manner

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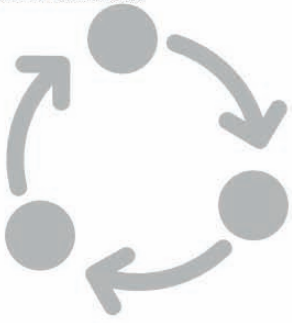
PRODUCT LIFECYCLE MANAGEMENT

It is also important to consider that the once your product is approved you will need to maintain the licence and renewals



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Components of Business Model

Build an agile organization

Think beyond the commercial model

In pursuing opportunities to differentiate themselves, companies should look beyond sales and marketing

Adjust to the needs of out-of-pocket and consumer markets

Out-of-pocket spend and private insurance make up a sizable share of healthcare expenditure in emerging markets

Capture opportunities

To capture opportunities in emerging economies, multinationals should carefully design their organizations to support their emerging-market strategy and withstand volatility

Organize emerging and developed markets separately

This allows strategies to be adapted to each type of market, gives emerging markets a voice in R&D and at the corporate level, makes it easier to rotate local talent and share best practices between markets[4]

Potential Hurdles and How to Overcome Them!

THINKING GLOBALLY BUT ACTING LOCALLY

DEVELOPMENT OF A STANDARDISED APPROACH WITH ROOM FOR FLEXIBILITY

INSIGHT-GATHERING INTO LOCAL MARKET TRENDS

DETERMINATION OF APPROPRIATE RESOURCE ALLOCATION

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CONCLUSION

"GOING FOR GOLD IN EMERGING MARKETS"

SUCESSS
Succeeding in emerging markets has been a challenging undertaking for multinational pharma companies, but those that adapt their end-to-end model for emerging markets could well thrive

GROWTH
Some emerging markets either suffered downturns or showed weaker growth forecasts as commodity prices fell; some healthcare systems struggled to scale up adequately their provision of care; and local companies became increasingly effective competitors in the pharma market.

ROLE
The pharmaceutical industry is quickly evolving; to stay relevant and competitive, companies need to stay on top of the most recent trends and technologies. One important piece of the puzzle that has been getting more recognition lately, and rightfully so, is the role of emerging markets.

LEADING
Defined by the Financial Times as "a developing country in which investment is estimated to lead to high income but with great risk"

EXPANSION
This shift towards emerging markets can be attributed to several economic and demographic factors, including increased life expectancy and prosperity, improved access to healthcare services and public or private funding, and growing populations

EASE
Emerging markets are "easy" targets for pharmaceutical companies, since effective treatments for most of these conditions are already available and could be easily marketed. However, the road is far from straightforward, and the strategies for expanding to these markets must be customised and take into account each region's specific healthcare needs, infrastructure, and regulations

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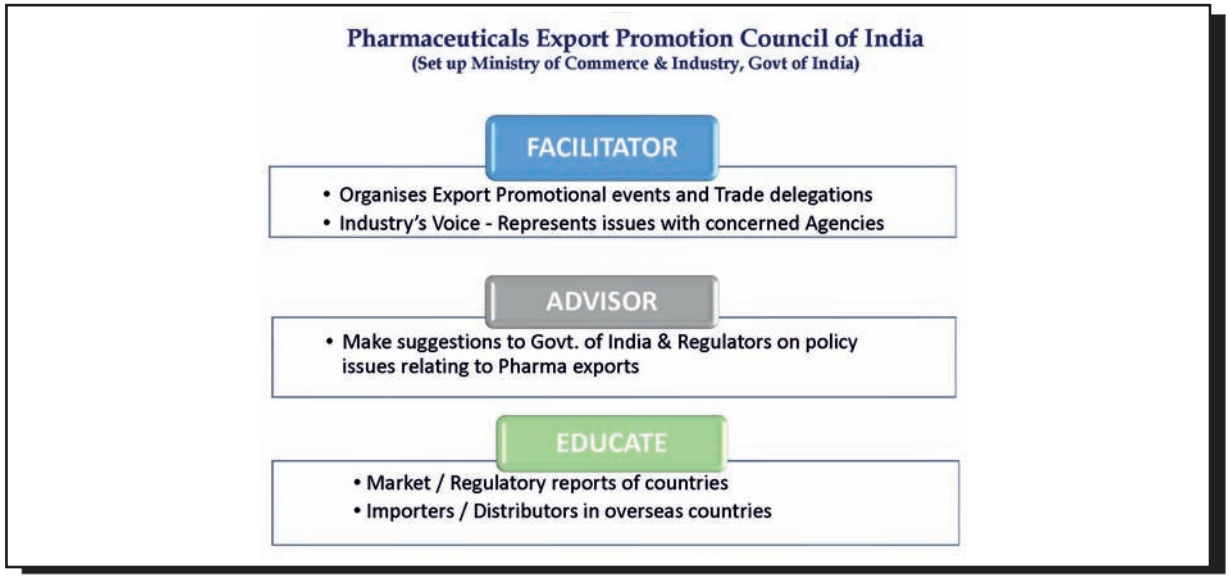
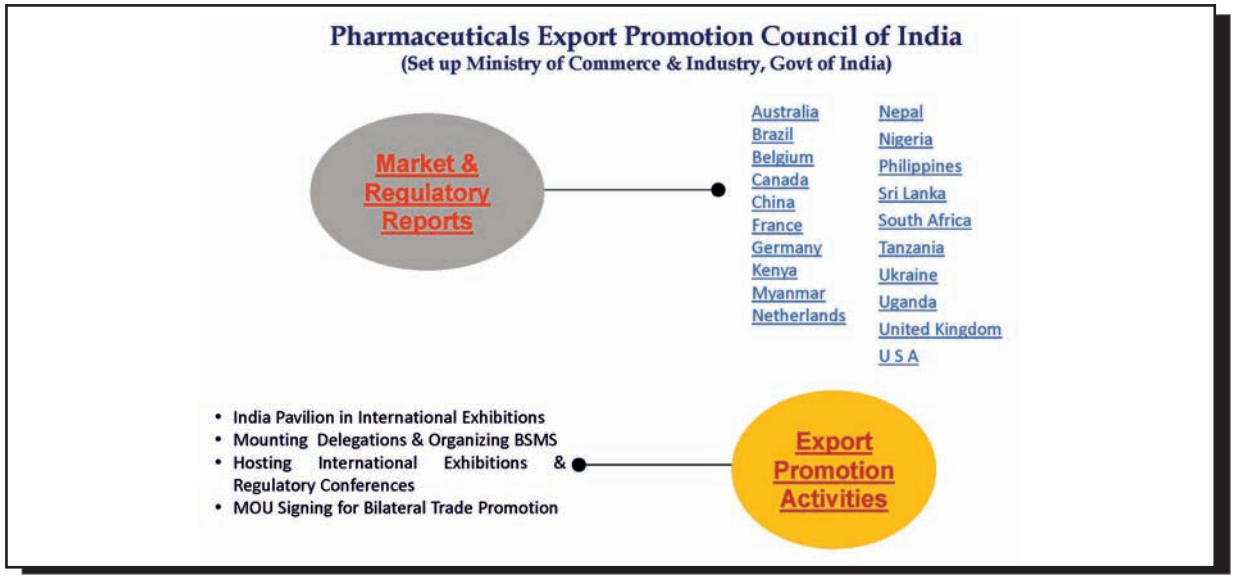
INDIAN PHARMA EXPORTS UNLOCKING THE POTENTIAL FOR SMEs

by

Ms. Lakshmi Prasanna. Ch,
Sr. Regulatory Affairs Officer, Pharmexcil
(Lecture Delivered during the Seminar on ""Recent Advancements in Regulatory landscape of India & Emerging Markets" held on 15th February 2020, conducted by Pharmexcil.)



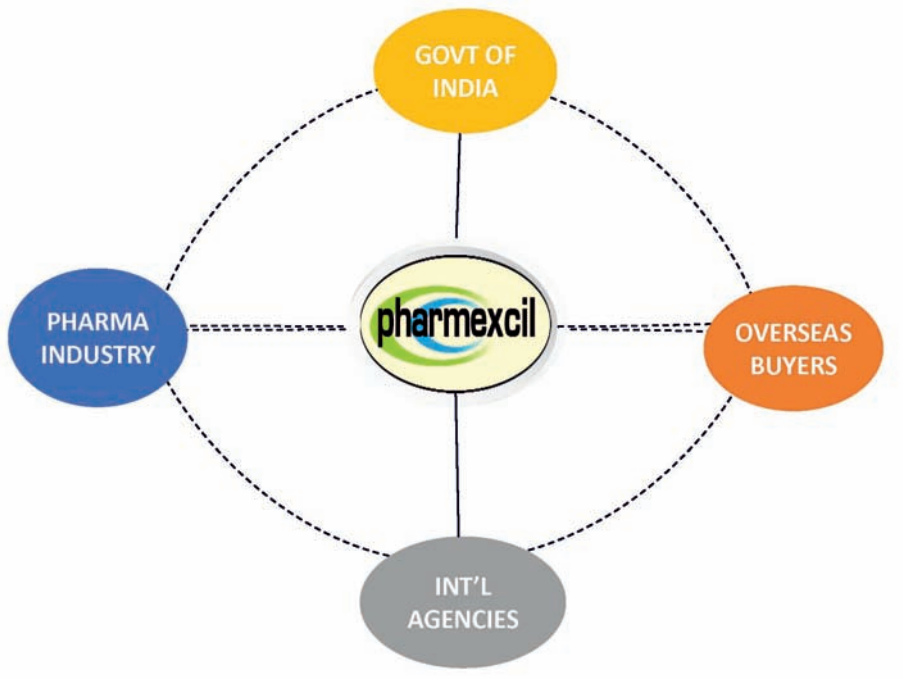


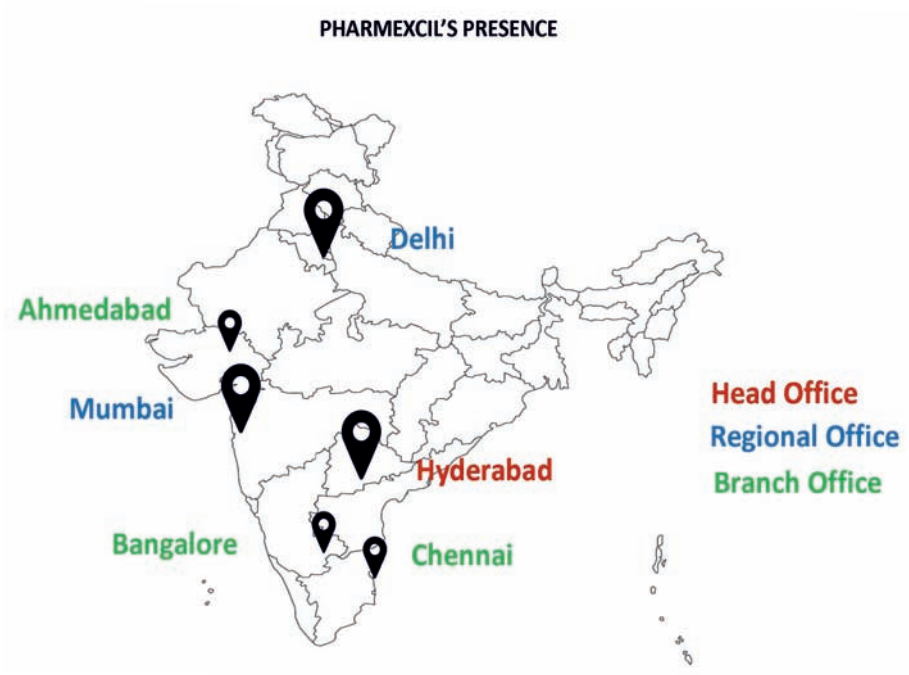
IPHEX

(International Exhibition for Pharma & Healthcare)

International Regulators Meet

International Regulatory Convergence to Promote Accessibility & Affordability of Quality Mediacies





Pharmexcil Membership

Registration Cum Membership Certificate (RCMC)

Category	Membership Fee (INR)	Entrance Fee (INR)	GST (18%) (INR)	Total (INR)
Large Scale Manufacturer	36,000/-	18,000 /-	9,720 /-	63,720/-
Small Scale Manufacturer	10,000/-	5,000/-	2,700/-	17,700/-
Merchant Exporter	12,000/-	6,000/-	3,240/-	21,240/-
Pharma Allied Exporter	12,000./	6,000.00 /-	3,240.00/-	21,240/
Note : Renewal Fee Every Financial Year (Membership Fee + GST)				

The membership fee of Rs.1000/- for the exporters with ZERO turnover w.e.f 15th August 2019.

Indian Pharma Industry

- India provides generic medicines to almost 180 countries.
- 3rd Largest exporter of formulations by volume & 10th by value
- 8 out of 20 Global Generic companies by 2018 values are from India
- 70% of WHO's vaccines requirement are sourced from India
- 90% of WHO Pre Qualified API's are sourced from India
- Thirty percent of US generic imports are sourced from India & India is the fourth Largest formulations Importing partner of USA

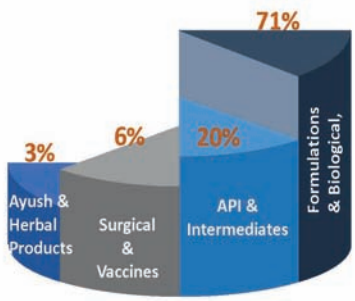
- No.of USFDA approved sites: 722 (as of July 2019)
- No.of EUGMP complied Units: 826 (as of July 2019)

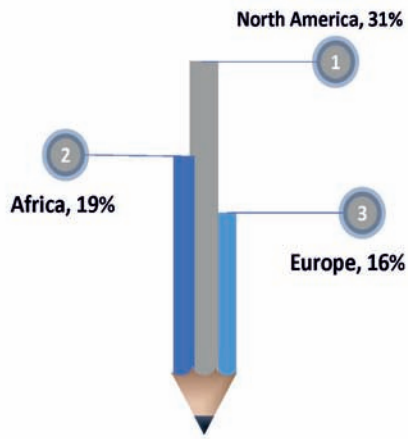
Indian Pharma Industry:
$ 43 Bn in FY 2019

India exported Generics worth $15 billion in 2019 Growing over 12 %.

Indian Pharmaceuticals: Export Outlook

Over 55% Exports of India are to Highly Regulated Markets





Major Export Destinations

India's Pharma exports During April-March$ Million USD

Category	Fy-18	Fy-19	Gr%	Contbn%
North America	5348.00	6145.67	14.92	32.12
Africa	3346.97	3436.44	2.67	17.96
EU	2752.64	3003.91	9.13	15.70
Asean	1181.45	1310.14	10.89	6.85
LAC	1135.15	1308.30	15.25	6.84
Middle East	869.05	1074.11	23.60	5.61
South Asia	764.33	812.84	6.35	4.25
CIS	733.17	788.27	7.52	4.12
Asia (Excluding Middle East)	627.30	693.62	10.57	3.62
Oceania	320.25	340.84	6.43	1.78
Other European Countries	150.99	162.86	7.86	0.85
Other America	52.48	57.38	9.33	0.30
Grand Total	17281.81	19134.49	10.72	100.00

Source: DGCIS

SME- Backbone of Pharma Industry

SME in Exports ?

Handholding Measures by Govt of India

Ministry of Commerce & Industry → MARKET ACCESS INITIATIVE SCHEME (MAI)

Dept of Pharmaceuticals
Ministry of Chemicals & Fertilizers →

- Pharmaceuticals Technology Upgradation Assistance (PTUA)Scheme
- Assistance to Bulk Drug Industry for Common Facility Centre
- Assistance for Cluster Development
- Pharmaceutical Promotion Development Scheme

MARKET ACCESS INITIATIVE SCHEME (MAI)

Financial Assistance from Govt to PHARMEXCIL Members

50% of claim – Max 2 Cr

1) Product Registration (PR)
2) Patent Filing (PA)
3) Bio Availability and Bio Equivalence Studies (BE)

The newly added components as per revised MAI guidelines are:

4) Plant Inspection Charges (PIC)
5) Expenses incurred for Obtaining Quality Certifications for Natural Products (AYUSH Products/Nutraceuticals) (EQC)
6) Expenses incurred for Implementation of Barcoding (EIB)

Claim within 90 days

https://pharmexcil.com/relevent-members-forms

Expenses incurred for Implementation of Bar-coding (EIB)

One-time grant – max **Rs.25 lakh** for charges incurred by small scale exporters for establishing bar coding facility

F.O.B value of exports <30 Cr

Pharmaceuticals Technology Up gradation Assistance (PTUS) Scheme

WHO-GMP

- To facilitate SMEs to upgrade their plant and machinery to WHO GMP standards
- Assistance in the form of **interest subvention** against sanctioned loan
- A total of Rs. 144 Crore has been earmarked for the scheme.
- The upper limit of interest subvention on loans **- 6% per** annum for a period of three years on reducing balance basis.
- The maximum loan eligible for this purpose will be **Rs. 4 Crore**, availed by the concerned SME

Assistance to Bulk Drug Industry for Common Facility Centre

- For creation of common facilities in any upcoming Bulk Drug Park promoted by State Governments/State Corporations

Captive Power Plants,
Steam and Cooling systems
Incubation facilities,
Common logistic facilities
Advance common testing Centre,
Regulatory awareness facilitation Centre Emergency Response

Rs. 100 Crore per Bulk Drug Park CFC or 70% of the project cost of CFC whichever is less

Assistance for Cluster Development

- For creation of common facilities in any pharma clusters including Bulk Drug, Medical Device, Ayurvedic, Unani and Cosmetics Units

- The Scheme would be implemented on a Public Private Partnership (PPP) format through one time grant-in-aid to be released in various to a Special Purpose Vehicles (SPVs) set up for the purpose

Rs.20.00 Cr per cluster or 70% of the cost of project whichever is less.

Pharmaceutical Promotion Development Scheme

- Aims at the promotion, development and export promotion in Pharmaceutical sector by extending financial support for conducting seminars, conferences, exhibitions, mounting delegations to and from India for promotion of exports as well as investments, conducting studies/ consultancies, for facilitating growth, exports as well as critical issues affecting Pharma sector.

MULTI FACETS OF A COMPETENT PHARMACIST

by

Ms. Heena. S ,
Vinayaka Mission's College of Pharmacy, Salem

Note: This article was awarded 2nd prize in the Essay Competition conducted by our Trust

INTRODUCTION: "Pharmacist" a person who is professionally qualified to prepare and dispense medicinal drugs. Multi competent Pharmacist has several knowledge about pharmacist field like identified and advocate for clinical problem-solving, decision-making, communication and education, evaluation and management, management of patient Traditionally, pharmacy has known as art and science of making medicines.

ROLE OF A PHARMACIST: Pharmacist, consult with client about over the counter medication for common ailments, instruct patient on how and when to take a prescribed medicine, supervise and train pharmacy technician, give prevent vaccination, provide health on healthy living.

CLINICAL PHARMACIST: We works in healthcare field and Work directly with physician, other health professional and patient to ensure that the medication prescribed for patient contribute to the best possible health outcomes. Taking patient medication history. Developing self administration scheme. Helping patient manage their own care, using electronic transfer of prescription. Running specialist clinics, carrying and prescribing review for the particular condition.

COMMUNITY PHARMACIST: We work in an independent (Retail) Pharmacy, dispensing of medicines, patient counseling, identifying and monitoring adverse drug reaction, demonstration of medical devices, maintaining patient medication records, health promotion, and nutritive advice.

AREA OF PHARMA INDUSTRY: Research and development: Drug discovery, reverse engineering, formulation, process development, upscalling from pilot to manufacture, trouble shooting, stability, and packaging materials.

- Production/Manufacturing: Production of bulk drugs and intermediates, finished medicines, vaccines and other biological products.
- Packaging: Various stages of packaging of pharmaceuticals.
- Quality Control: Product testing throughout the life cycle of the drug and finished product.

- Quality Assurance: Preparing, reviewing and submitting documents, conducting training, internal audits etc., Assuring overall quality management.
- Sales and marketing: Strategic planning, team management and marketing of pharmaceuticals. Working as a medical representative.
- Regulatory Affairs: Preparing, reviewing, communicating, submitting, registration documents on pharmaceutical to regulatory agencies to get R&D, testing, production and marketing approvals, issues related to patent.

CATEGORIES OF COMPETENT PHARMACY: Multi disciplinary team work, Leadership and management, self management, Inter-personnel skills, personnel and professional, patient focused care, research and evaluation, public health, working with specific client group, prescribing support to organisation, medicines administration support, using new technology, existing core practice. Pharmacists are an essential part of the healthcare multidisciplinary team. They help to ensure that medicines are used in the safest and most effective manner.

1. **CARE GIVER:** Practices integrated and caring services along with other health professionals in the healthcare system.
2. **LEADER:** Performs as a leader for the overall welfare of the patient and community.
3. **TEACHER:** Educates next generation.
4. **LIFE LONG LEARNER:** Develops skills and updates knowledge as an ongoing process.
5. **MANAGER:** Manages Men, Material, and Machine.
6. **RESEARCHER:** Uses evidence base to advise on rational use of medicines and provides unbiased health information.
7. **COMMUNICATOR:** Link between the prescriber and patient. Communicates health information to patient.
8. **DECISION MAKER:** Ability to evaluate, synthesize data and provide efficacious, safe and cost effective use of medicines.

ETICAL PRINCIPLES: The code of ethics, formulated by the Pharmacy Council of India, for the guidance of Indian Pharmacist is meant to guide the Pharmacist as to how should conduct himself, his patients and general public, his colleagues, members of the medical and other health professionals. They can separate into five categories. The responsibility for the consumer, The community, The profession, The business and the wider healthcare team

PROFESSION OF PHARMACY: In handling, selling, distributing, compounding, and dispensing of medical substances, including poisons, and potent drugs, a pharmacist in collaboration with medical men and others is endowed with the responsibility of safeguarding the health of the people. The pharmacist must understand their responsibility and fulfill their duties honorably keeping in mind the well being of the society. The pharmacist must be a good citizen and must uphold and defend the law of the state and the nation

PHARMACIST IN RELATION TO HIS JOB: The appearance of the place should reflect the professional character of pharmacy and indicate to the public that the practice of pharmacyis carried out in the establishment. They should be qualified pharmacist having personal control over the pharmacy.

HANDLING OF PRESCRIPTION: When a prescription is presented for dispensing, it should be received by a pharmacist without any comment or discussion over it, regarding the merits and demerits of its therapeutic efficiency. It is not within the capacity of a pharmacist to add, omit or substitute any ingredient or alter the composition of a prescription without the consent of the prescriber.

HANDLING OF DRUGS: Prescription should be correctly dispensed with drugs for standard quality. All the ingredients must be weighed correctly and must be in exact proportions.

PHARMACIST IN RELATION TO HIS TRADE: Price structure, Fair trade practice, Purchase of drug, Hawking of drugs, Advertising and display.

PHARMACIST IN RELATION TO MEDICAL PROFESSION: Pharmacist should practice medicine. No pharmacist should recommend a medical practitioner, in particular. Pharmacist should be never entering into secret arrangement with practitioner to offer them commission by recommending his dispensary or drug store. He should maintain strictly the professional secrecy, unless required to do so by law. The Pharmacist must be a law abiding citizen and must fulfil the provision of the pharmaceutical and other law and regulation. He should have relationship with his own professional organization. He should maintain the dignity, decorum, decency and propriety of his profession.

CONCLUSION: Pharmacist are one who work behind this counter providing knowledge of evaluating prescription and establishing a comfortable counselling to individuals leading to a immense confidence of unfolding the diversity of condition. “IT IS EASY TO GET A THOUSAND PRESCRIPTIONS BUT HARD TO GET ONE SINGLE REMEDY.”

INFORMATION

M. PHARM & PHARM D SCHOLARSHIPS 2019-20 AWARDED BY TNPSWT

Profile of 1rd Rank

PHARMACEUTICS

Name: Ms. S. Priya Dharshini
Project Title: Formulation and Evaluation of Poly Herbal Antidandruff Gel
College: Periyar College of Pharmaceutical Sciences, Tiruchirappalli
Guide's Name: Dr. K. Reeta Vijaya Rani

PHARMACEUTICAL CHEMISTRY

Name: Ms. Vinodhini. M
Project Title: Design, Synthesis and Study of some novel N-Substituted Phthalimide Derivatives against Targeted enzyme for their Anti-cancer and Anti-microbial activity
College: College of Pharmacy, Mother Theresa Post Graduate & Research Institute of Health Sciences, Puducherry
Guide's Name: Dr. K. Girija

PHARMACEUTICAL ANALYSIS

Name: Ms. Tresa Thomas
Project Title: HPTLC method development and validation for the estimation of Levamisole and Mebendazole in bulk and in-vitro interaction study of Mebendazole with Atorvastatin
College: College of Pharmacy, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore
Guide's Name: Dr. T. K. Ravi

PHARMACOLOGY

Name: Ms. Arthy. M
Project Title: Investigate the Combined Effect of Melatonin And Fluvastatin In Dexamethasone Induced Osteoporosis in Experimental Animal
College: College of Pharmacy, Mother Theresa Post Graduate & Research Institute of Health Sciences, Puducherry
Guide's Name: Mr. J. Gopi Sudheer Kumar

PHARMACOGNOSY

Name: Ms. R. Harini

Project Title: Marine Pharmacognostical Study, Leading to the Design and Formulation of Repellent for Genetically Mutant Mosquitoes.

College: College of Pharmacy, Mother Theresa Post Graduate & Research Institute of Health Sciences, Puducherry

Guide's Name: Prof. Dr. V. Gopal

PHARMACY PRACTICE

Name: Ms. Dharani. M

Project Title: Assessment of Clinical Pharmacy Interventions for Safer Use of Medicines in Elderly Patients- A Prospective Observational Study

College: Faculty of Pharmacy, Sri Ramachandra Institute of Higher Education and Research, Chennai

Guide's Name: Dr. P. Seenivasan

PHARM D- PHARMACY PRACTICE

Name: Ms. Ashna Chackochan, Ms. Mahima Maheshwari, Mr. Ajith JS

Project Title: Dosage Optimization of Leflunomide in South Indian Patients: A Population Based Pharmacokinetic and Pharmacodynamic Study.

College: JSS College of Pharmacy, Ooty

Guide's Name: Dr. Arun K P

NOTIFICATION

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 16th March, 2020

G.S.R. 180 (E).—Whereas the Central Government is satisfied that the use of the drugs Chenodeoxycholic acid and Ursodeoxycholic acid, extracted and prepared from porcine sources, are likely to involve certain risk to human beings and animals and that it is necessary and expedient to prohibit the import of the said drugs in the public interest;

Now, therefore, in exercise of the powers conferred by section 10A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby makes the following amendment in the notification of the Government of India in the Ministry of Health and Family Welfare number G.S.R. 577(E), dated the 23rd July, 1983, namely:—

In the said notification, in the Table, after serial number 13 and the entry relating thereto, the following serial number and entry shall be inserted, namely:—

"14. Chenodeoxycholic acid extracted and prepared from porcine sources.

15. Ursodeoxycholic acid extracted and prepared from porcine sources.".

[F.No. X.11014/1/2020-DR]
Dr. MANDEEP K. BHANDARI, Jt. Secy.

Note: The principal notification was published in the Gazette of India, Extraordinary, Part II, section 3, sub-section (I)vide notification number G.S.R. 577(E), dated the 23rd July, 1983 and lastly amended vide notification number G.S.R. 52(E), dated the 27th January, 2020.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 11th February, 2020

G.S.R. 101 (E).—Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, was published as required under sub-section(1) of section 12 and sub-section(1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) vide notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R. 447(E), dated the 24th June, 2019, in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i), inviting objections and suggestions from persons likely to be affected thereby before the expiry of a period of thirty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas copies of the said Official Gazette were made available to the public on the 24th June, 2019;

And whereas objections and suggestions received from the public on the said rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred under sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely:—

1. (1) These rules may be called the Drugs and Cosmetics (Amendment) Rules, 2020.

(2) They shall come into force on the 1st day of March, 2021.

2. In the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as the said rules), in rule 2,-

(i) existing clause (ea) shall be re-lettered as clause (eb), and before clause (eb) as so re-lettered, the following clause shall be inserted, namely:—

'(ea) "Marketer" means a person who as an agent or in any other capacity adopts any drug manufactured by another manufacturer under an agreement for marketing of such drug by labeling or affixing his name on the label of the drug with a view for its sale and distribution;' ;

(ii) existing clauses (ea) and (eb) shall respectively be re-lettered as (eb) and (ec).

3. In the said rules, after rule 84C, the following rules shall be inserted, namely:—

"84D. Agreement for marketing.- No marketer shall adopt any drug manufactured by another manufacturer for marketing of such drug by labeling or affixing his name on the label of the drug with a view for its sale and distribution without an agreement as referred to in clause (ea) of rule 2.

84E. Responsibility of marketer of the drugs.- Any marketer who sells or distributes any drug shall be responsible for quality of that drug as well as other regulatory compliances along with the manufacturer under these rules."

4. In the said rules, in rule 96, after sub-clause (xii) of clause (1), the following sub-clause shall be inserted, namely:—

"(xiii) The name of the marketer of the drug and its address, in case the drug is marketed by a marketer:

Provided that if the drug is contained in an ampoule or a similar small container, it shall be enough if only the name of the marketer is shown."

[F. No. X.11014/22/2018 -DR]
Dr. MANDEEP K. BHANDARI, Jt. Secy.

Note:- The principal rules were published in the Official Gazette vide notification number F.28-10/45-H (1) dated 21st December, 1945 and last amended vide notification number G.S.R. 828(E), dated the 6th November, 2019.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 11th February, 2020

S.O. 648(E).— In pursuance of sub-clause (iv) of clause (b) of section 3 of the Drugs and CosmeticsAct, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby specifies the following devices intended for use in human beings or animals as drugs with effect from the 1st day of April, 2020, namely:—

All devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of —

(i) diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;
(ii) diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability;
(iii) investigation, replacement or modification or support of the anatomy or of a physiological process;
(iv) supporting or sustaining life;
(v) disinfection of medical devices; and
(vi) control of conception.

[F.No. X.11035/281/2018-DRS]
Dr. MANDEEP K. BHANDARI, Jt. Secy.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 27th January, 2020

G.S.R. 52(E). Whereas the Central Government, on being satisfied that the use of the drug Oxytocin and its formulation in any name or manner is likely to involve certain risk to human beings and animals, prohibited the import of the said drugs in public interest by amending the notification number G.S.R. 577(E), dated the 23rd July, 1983 vide notification of the Government of India in the Ministry of Health and Family Welfare number G.S.R. 390(E), dated the 24th April, 2018;

And whereas, subsequent to issuance of the said notification number G.S.R. 390(E), dated the 24th April, 2018 for prohibition of import of drug Oxytocin and its formulation in any name or manner, the Central Government received representations from various stakeholders to allow import of Oxytocin reference standards for the purpose of examination, test or analysis;

And whereas, the Central Government is satisfied that import of Oxytocin reference standards is necessary exclusively for the purpose of examination, test or analysis before carrying out commercial manufacturing of the said drug;

Now, therefore, in exercise of the powers conferred by section 10A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby makes the following amendment in the notification of the Government of India in the Ministry of Health and Family Welfare number G.S.R. 577(E), dated the 23rd July, 1983, namely:-

In the said notification, in the Table, for serial number 12 and the entry relating thereto, the following serial number and entry shall be inserted, namely:-

"12. Oxytocin and its formulation in any name or manner except Oxytocin reference standards imported exclusively for the purpose of test and analysis."

[F. No. X.11014/2/2018-DR]
Dr. MANDEEP K. BHANDARI, Jt. Secy.

Note: The principal notification was published in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i) vide G.S.R. 577(E), dated the 23rd July, 1983 and lastly amended vide notification number G.S.R. 1074(E), dated the 30th October, 2018.

NEWS

US FDA Approves First Generic Version of $750 Daraprim Drug

The U.S. Food and Drug Administration, approved the first generic version of Daraprim, a drug used to treat a disease resulting from a parasite infection.

Daraprim came under the spotlight after a company once run by "pharma bro" Martin Shkreli bought the rights to the drug and then quickly raised the price from $17.50 per tablet to $750, while also taking steps to ensure there would not be a cheaper generic version of the medicine.

The drug is used to treat toxoplasmosis, a disease that causes flu-like symptoms and occurs usually by eating undercooked contaminated meat.

The disease is considered to be the leading cause of death due to food borne illness in the United States, the U.S. health regulator said.

The agency gave the approval to Cerovene Inc for a generic version of Daraprim.

"Today's approval is especially important for populations that are more susceptible to toxoplasmosis infections, such as pregnant women and individuals with HIV or AIDS," FDA Commissioner Stephen Hahn said.

The FDA has been trying to address the challenge of closing loopholes that allow brand-name drug companies to delay generic competition.

Source: *ET Healthworld,* 29th February 2020

Piramal to Invest Rs 300cr in New Plant

Piramal Glass Ltd (PGL) will invest Rs 300 crore to set up a plant at Jambusar near Bharuch.

The glass packaging solutions major which caters to high-end cosmetics, perfumery, food and beverage and pharmaceutical industry will set up one new furnace with seven new manufacturing on a 3 lakh sqft land.

"The plant will commence manufacturing from December this year. It will manufacture speciality bottles catering to Indian, Asian, European and the US markets," said Vijay Shah, executive director, PGL.

Shah said that the company will invest another Rs 120 crore in its Kosamba plant and hire a total of 1,000 new employees during expansion in Jambusar as well as Kosamba.
PGL has a global sales of Rs 2,500 crore and it operates from India, Sri Lanka and the US. The firm's current manufacturing capacity is 540 tonnes per day and with the new Jambusar plant, it will add another 250 tonnes per day to its capacity. The firm provides end-to-end glass packaging solutions in nearly 50 countries.

Source: *ET Healthworld,* 2nd March 2020

Niti Aayog, Health Ministry Reach Consensus on Medical Devices Bill

Government think tank Niti Aayog and the health ministry have arrived at a consensus on the Medical Devices Bill, according to sources, ending months of wrangling over several issues, including what will encourage domestic manufacturing.

Sources told ET that the final draft of the Medical Devices (Safety, Effectiveness and Innovation) Bill, 2019, proposes that medical devices should be regulated by a separate division under the Central Drugs Standard Control Organisation (CDSCO).

"All stakeholders have arrived at a consensus over the bill and we will soon make a presentation before the PMO (Prime Minister's Office) for their approval," one of the people cited earlier told ET, requesting not to be named.

The division that will monitor medical devices will be headed by a technical expert, and there will be no separate regulator, as conceptualised by the Aayog earlier.

Besides, the regulation of the devices will be under a separate Act and not under the Drugs and Cosmetics Act, 1940, as was being pushed by the health ministry.

This follows several rounds of discussions over the last few months to resolve the impasse created by the Aayog and the ministry pushing their own prescriptions.

A consensus was arrived at after the PMO intervened, given the urgency to push domestic manufacturing of medical devices in a big way to bring down costs as well as reduce imports.

However, the decision to use IIT labs for certification of these devices, as well as ensuring that certification is of global standards and there is no need for dual certification, would be taken up at a later stage once the Bill is passed by Parliament, the person cited earlier.

The ministry will soon move a cabinet note on this. After approval, the Bill will be tabled in Parliament.

The CDSCO, under the health ministry, regulates the safety, efficacy and quality of notified medical devices under the provisions of the Drugs and Cosmetics Act, 1940, and Rules made there under.

However, this has been a bone of contention between the ministry and the Aayog, with the latter being of the view that drugs and devices are two different things and cannot be regulated by a drug expert.

Currently, only 23 categories of medical devices are regulated in India under the Drugs and Cosmetics Act.

At over $15 billion, India's medical devices market is the fourth largest in Asia after Japan, China and South Korea, and is projected to grow to $50 billion by 2025. India imports 80% of its medical devices.

Source:*ET Healthworld,* 2nd March 2020

SC Annuls Orchid Pharma Sale Plea, Accord Life Suffers Setback

The Supreme Court (SC) has set aside the injunction order of National Company Law Appellate Tribunal (NCLAT) which stayed the sale of Orchid Pharma to Dhanuka Labs citing the bid price was lower than liquidation value.

The NCLAT stay was granted in response to a petition filed by Accord Life Spec Private Ltd., a company promoted by DMK MP Jagatrakshagan's family members.

It also ordered that SBI be impleaded in the case as one of the respondents. SBI moved the apex court and sought quashing of the NCLAT injunction.

Pursuant to the ongoing Corporate Insolvency Resolution Process (CIRP), we hereby inform that the appeal filed before the SC was disposed of on February 28, 2020. "Accordingly, the appeal filed in SC was allowed and the judgement of the NCLAT was set aside," Orchid said in a stock exchange filing.

The Court said, "No provision in the Code (IBC) or Regulations has been brought to our notice under which the bid of any Resolution Applicant has to match liquidation value."

The Chennai bench of NCLT approved the resolution plan of Dhanuka Laboratories for Rs 570 crore, to take over Orchid Pharma under the Insolvency and Bankruptcy Code (IBC).

The liquidation value was Rs 1309 crore.

The resolution plan of Dhanuka Laboratories was lower than Orchid Pharma's liquidation value of Rs 1,309 crore. The bench noted that it was more concerned about the 1,407 employees of Orchid Pharma, who were seeking their livelihood by working in this company.

This was the second bid for Orchid that faced a regulatory bump. Ingen capital submitted a bid for Rs 1000 crore, but failed to bring in the funds which resulted in the collapse of the transaction. The RP was ordered by the NCLAT to call for fresh bids, which resulted in Dhanuka getting the nod.

Source:*ET Healthworld,* 4th March 2020

Low-dose Aspirin Linked to Reduced Liver Cancer Risk : Study

Among adults with chronic viral hepatitis at high risk of liver cancer, those who took low-dose aspirin long-term were less likely to develop liver cancer or to die from liver-related causes. The findings come from a study published in the New England Journal of Medicine and conducted by a team led by investigators at Karolinska Institutet and Örebro University Hospital in Sweden and Massachusetts General Hospital in the U.S.

"Rates of liver cancer and of mortality from liver disease are rising at an alarming pace in the U.S. and European countries," says lead author Tracey Simon, researcher at the Division of Gastroenterology and Hepatology at Massachusetts General Hospital. "Despite this, there are no established treatments to prevent the development of liver cancer, or to reduce the risk of liver-related death."

For the analysis, investigators examined information from Swedish registries on 50,275 adults who had chronic viral hepatitis, a type of liver infection that is caused by the hepatitis B or C virus and is the most common risk factor for liver cancer. Over a ten-year period, 4.0 percent of patients who took low-dose aspirin (less than 163 mg/day) and 8.3 percent of nonusers of aspirin developed liver cancer. Aspirin users had a 31 percent lower relative risk of developing liver cancer.

Importantly, the study showed that the longer a person took low-dose aspirin, the greater the benefit. Compared with short-term use (3 months to 1 year), the risk of liver cancer was 10 percent lower for 1–3 years of use, 34 percent lower for 3–5 years of use, and 43 percent lower for 5 or more years of use. Also, liver-related deaths occurred in 11.0 percent of aspirin users compared with 17.9 percent of nonusers over 10 years, representing a 27 percent lower relative risk for those who took the medication.

The benefits were seen regardless of sex, severity of hepatitis, or type of hepatitis virus (B or C). The risk of internal bleeding – a concern when taking aspirin long-term – was not significantly elevated among aspirin users.

"This is the first large-scale, nationwide study to demonstrate that the use of aspirin is associated with a significantly reduced long-term risk of liver cancer and liver-related mortality," says senior author Jonas F. Ludvigsson, professor at the Department of Medical Epidemiology and Biostatistics at Karolinska Institutet.

Source: *ET Healthworld,* 12th March 2020

Dr Reddy's Launches Generic Opioid Antagonist Injection in US

Drug firm Dr Reddy's Laboratories, said it has launched generic Naloxone Hydrochloride injection, and indicated for complete or partial reversal of opioid depression, in the US market. The company has launched Naloxone Hydrochloride injection USP, 2 mg/2 mL (1 mg/mL) single-dose prefilled syringe after the approval from the United States Food and Drug Administration (USFDA), Dr Reddy's said in a statement.

The product is a generic version of ADAPT Pharma Operations Ltd's Narcan injection, it added.

"We are pleased to bring our second product to market that has been designated as a Competitive Generic Therapy (CGT) by the USFDA," Dr Reddy's Laboratories North America Generics CEO Marc Kikuchi said.

With a CGT designation, the company has 180-day CGT exclusivity to market this product, he added.

According to IQVIA Health data, Naloxone Hydrochloride injection USP, 2 mg/2 mL (1 mg/mL) had US sales of around USD 31 million (about Rs 230 crore) moving annual total for the most recent twelve months ended in January 2020.

Source: *ET Healthworld,* 19th March 2020

Insulin Gains New Pathway to Increased Competition : USFDA

Today is a historic day and a landmark moment for patients with diabetes and other serious medical conditions, as insulin and certain other biologic drugs transition to a different regulatory pathway. This regulatory transition, mandated by Congress and implemented by the FDA, is incredibly important for patients. For the first time, a pathway will be open for products that are proposed as biosimilar to, or interchangeable with, the transitioned products. The availability of safe and effective biosimilar and interchangeable versions of these treatments, including insulin, is expected to increase patient access, adding more choices and potentially reducing costs of these vital therapies.

Biologic drugs, including insulin, treat some of the most serious diseases and conditions. The drugs transitioning today are used in the treatment, diagnosis and prevention of many of these conditions, including diabetes, respiratory distress syndrome, fertility conditions, Cushing's syndrome, deep vein thrombosis, Gaucher disease and many more. But these life-saving drugs often also contribute significantly to drug costs. Historically, it was more difficult to develop generic versions of these drugs under the Federal Food, Drug and Cosmetic (FD&C) Act due to scientific challenges and limitations on the scope of data that can be relied upon in a generic drug application. This framework contributed to limited competition for these drugs, resulting in fewer choices and higher prices for patients. Today's transition opens a new pathway for manufacturers to seek FDA approval of and bring biosimilar and interchangeable versions of insulin and other transitioning products to market, facilitating greater competition.

Source: *ET Healthworld,* 23rd March 2020

Aurobindo, Sandoz Call off USD 900mn Deal

Aurobindo Pharma, said the USD 900 million deal to acquire Sandoz Inc's US-based generic oral solids and dermatology businesses, has been mutually called off. "The decision was taken as approval from the US Federal Trade Commission for the transaction was not obtained within anticipated timelines," Aurobindo Pharma said in a regulatory filing.

In September 2018, Aurobindo Pharma had said its US subsidiary has entered into a pact to acquire commercial operations and three manufacturing facilities in America from Sandoz Inc, USA, for USD 900 million.

The acquisition was to be made through its wholly-owned subsidiary, Aurobindo Pharma USA Inc.

The transaction if completed would have positioned the Hyderabad-based firm as the second largest dermatology player and the second largest generics company in the US by prescriptions

Source: *ET Healthworld,* 2nd April 2020

Cipla Completes Successful Phase-3 Clinical Study of Generic Asthma Drug

Pharma major Cipla, announced the successful completion of Phase-3 clinical study for generic fluticasone propionate and salmeterol inhalation powder indicated for treatment of asthma and chronic obstructive pulmonary disease. The study results demonstrate that Cipla's fluticasone propionate and salmeterol inhalation powder 100/50 mcg is therapeutically equivalent to Advair Diskus 100/50 mcg, Cipla said in a statement.

The Phase-3 study, which successfully completed in the first attempt, was conducted over a period of 15 months at over 100 sites in the US enrolling 1,400 asthma patients, it added.

"This is an important milestone and is a testament to Cipla's strong respiratory capabilities and will go a long way in strengthening our respiratory franchise in the US," Cipla MD and Global CEO Umang Vohra said.

Unmatched presence across the care continuum and the widest range of drug-device combinations has established Cipla's position as a lung leader in India and other key emerging markets, he added.

"Our endeavour is to extend this expertise across developed markets through niche product development," Vohra said.

According to IQVIA, Advair Diskus and its generic equivalents registered a total US sales of approximately USD 2.9 billion for the 12-month period ending February 2020, Cipla said.

The product is indicated to treat asthma in patients of 4 years and older as a twice-daily prescription medicine and in long-term to treat chronic obstructive pulmonary disease, including chronic bronchitis, emphysema, or both, for better breathing and fewer flare-ups, it added.

Source: *ET Healthworld,* 2nd April 2020

Lupin Launches Generic Drug Used for Prevention of Organ Rejection In Kidney Transplant In US

Drug firm Lupin said it has launched generic Mycophenolic acid delayed-release tablets, which is used to prevent organ rejection in patients receiving kidney transplants in the US market. The company has launched the tablets in the strengths of 180 mg and 360 mg, Lupin said in a statement.

Company's alliance partner Concord Biotech Ltd had received an approval from the United States Food and Drug Administration (USFDA) earlier for the product, it added.

The tablets are generic version of Novartis Pharmaceuticals Corporation's Myfortic delayed-release tablets, 180 mg and 360 mg, Lupin said.

According to IQVIA MAT February 2020 data, Mycophenolic acid delayed-release tablets USP had an annual sales of around USD 156 million in the US, it added.

Source: *ET Healthworld,* 6th April 2020

All Med Devices Now Classified as 'Drugs': Govt

Amid concerns related to rise in prices of essential commodities and pharmaceutical products in the wake of the Covid-19 outbreak, the Centre notified all medical devices sold in the country as 'drugs' from April 1, bringing them under the purview of price control and prohibiting companies from increasing prices of these products by more than 10% annually.

"Medical device intended for use in human beings or animals have been notified as drugs with effect from April 1, 2020, all medical devices shall accordingly be governed under the provisions of Drug Price Control Order, 2013," an order by the National Pharmaceutical Pricing Authority (NPPA).

Following this order, all medical devices used to treat a patient — be it syringes, needles, cardiac stents, knee implant, digital thermometers, CT scan, MRIs, dialysis machines — will be under government regulation.

As per the notification, four medical devices — cardiac stents, drug eluting stents, condoms and intra uterine devices (Cu-T) — are scheduled medical devices for which ceiling prices have been fixed.

The objective of the order is to ensure that no manufacturer or importer increases the price of a drug by more than 10% of the MRP during the preceding 12 months.

NPPA said the price control order was "a major tool in the fight with the emerging situation due to Covid-19".

NPPA has also asked states to ensure availability of essential medical commodities, including personal protection equipment, masks, sanitisers, gloves, testing kits etc. In a letter to chief secretaries, the NPPA head asked states to assess stock situation of essential commodities for the next two months and also inform the Centre about production and availability details.

Source: *ET Healthworld,* 2nd April 2020

Pharma Exports to Miss USD 22 billion Target Due to Lockdown: Official

Pharma exports from India may witness a dip in growth due to ongoing lockdown and also export restrictions imposed on certain drugs, a top official of Pharmaceuticals Export Promotion Council, a body under the Ministry of Commerce which earlier estimated that exports may cross USD 22 billion in FY 20 has said. Udaya Bhaskar, Director General of Pharmexcil said Pharma exports were pegged at USD 19.14 billion during the last fiscal.

He also said the global situation of coronavirus spread became unpredictable with each country imposing certain tailor-made restrictions.

He said the exports in March 2019 alone stood at USD 2.1 billion which prompted the exports estimation to be pegged at USD 22 billion for the Fy20.

The exports were at USD 17.28 billion during 2017- 18.

India restricted exports of Paracetamol and Hydroxychloroquine, among some other drugs to other countries in view of their perceived role in Covid-19 treatment.

"As far as exports are concerned, since there are several restrictions, we may cross last years figure. Last year we did USD 19.14 billion worth of pharma exports. By February ending this year we achieved USD 18.74 billion. Even if there is a big dip in March, the figure may cross last (fiscal) year's mark," the official told".

According to him, India started getting some Active Pharmaceutical Ingredients (API) from China though it is still becoming difficult for the bulk drug to reach its destinations.
He said as of now there is no difficulty in getting API imports.

The exports' promotion body recently wrote a letter to the Director General of Foreign Trade (DGFT) highlighting some of the problems being faced by the exporters with regard to getting the license for Restricted Export Item (Non SCOMET) for the listed products.

The body said member-exporters are having a commitment through Irrevocable Commercial Letter of Credit (ICLC) before the date of imposition of restriction.

And there "undue delays in issue of licenses" resulting in huge penalties for delayed supplies, loss of trust and credibility, demurrages for the shipments lying in ports and ultimately making them in a disadvantageous position of losing their valued importers, it told DGFT.

"We therefore request you (DGFT) to issue the license/NOC for our member exporters on fast track mode to enable them to export the listed products which are of therapeutic use in the symptomatic treatment of COVID-19," the letter said.

The Pharmexcil also requested the DGFT to exempt EOU (Export Oriented Units) from getting NOCs to export.

An earlier notification by the DGFT exempted units located in SEZs and under Advance Licensing Scheme from the export restrictions.

According to industry sources, Paracetamol, Hydroxychloroquine and other drugs which were put under restriction for exports constitute about USD 600 million per annum in overall Pharma exports.

A Pharma expert opined the export restriction by India which is regarded as "pharmacy of the world", on export of some of the drugs is not justified as the whole world is fighting united against coronavirus spread.

Source:*ET Healthworld,* 6th April 2020

Natco Launches Cut-Price Copies of Astrazeneca's Patented Anti-Diabetes Drug

Amid serious global attention on Covid-19 pandemic, India's Natco Pharma has quietly launched the generic versions of AstraZeneca's patented anti-diabetes brand Farxiga. Natco named its brand Dapnat, which will be available in 5mg and 10mg strengths. These products will be priced significantly lower than the two strengths of Farxiga (dapagliflozin) sold in India.

While Natco has priced its two products at INR 15 and INR 19.50 respectively, AstraZeneca's Farxiga costs INR 49 and INR 57 for each tablet.

The launch gives Natco an entry in the rapidly growing SGLT-2 segment that has mostly been dominated by global drug makers. However, for roughly a year, the segment has seen the entry of Indian drug maker Glenmark, which launched its versions of remogliflozin at a significantly lower price than MNC brands.

According to information available, AstraZeneca has two patents on dapagliflozin in India, the first of which expires later this year in October and the other in 2023. There is no clarity on any injunction moves by AstraZeneca against Natco, since Indian courts are closed due to the continuing nationwide lockdown to control the spread of Covid-19.

Natco has been consistently launching generic versions of patented drugs at low prices. Last December, it launched cut-price versions of AbbVie's anti-cancer brand Imbruvica in India.

While health activists have welcomed such moves, these have drawn international flak from pro-patent lobby groups. The US government representatives have criticized India for allowing loopholes that failed to protect intellectual property rights of global companies.

Source: *ET Healthworld,* 7th April 2020

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